

# Vir Biotechnology Announces Completion of Enrollment in ECLIPSE 1 Phase 3 Trial for Chronic Hepatitis Delta

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- ECLIPSE 1 estimated date of last participant reaching primary endpoint (primary completion) in the fourth quarter of 2026, and topline data expected in the first quarter of 2027
- ECLIPSE registrational program on target, with ECLIPSE 2 and 3 enrolling well and in line with the Company's expectations
- Swift recruitment underscores high unmet medical need for effective and convenient chronic hepatitis delta treatment

SAN FRANCISCO--(BUSINESS WIRE)-- Vir Biotechnology, Inc. (Nasdaq: VIR) today announced the completion of enrollment for ECLIPSE 1, a Phase 3 trial evaluating the safety and efficacy of the combination of tobevibart and elebsiran in patients with chronic hepatitis delta (CHD). ECLIPSE 1 is one of three trials in Vir Biotechnology's ECLIPSE registrational program for CHD, and it is designed to provide the efficacy and safety data needed for potential submission to global regulatory agencies, including in the U.S. and Europe. Enrollment in the other two trials in the program, ECLIPSE 2 and ECLIPSE 3, is ongoing and on track. The last patient in ECLIPSE 1 is expected to reach the trial's primary endpoint (primary completion date) in the fourth quarter of 2026, with topline data expected in the first quarter of 2027.

"Reaching full enrollment in our ECLIPSE 1 Phase 3 clinical trial marks an essential milestone as we work towards submission of the combination of tobevibart and elebsiran for the treatment of chronic hepatitis delta to global regulatory agencies," said Marianne De Backer, M.Sc., Ph.D., MBA, Chief Executive Officer, Vir Biotechnology. "We are dedicated to advancing our registrational program with utmost urgency to deliver a much-needed new treatment option for people living with hepatitis delta."

“The strong interest and participation in ECLIPSE 1 reflect the urgent need for innovative solutions in chronic hepatitis delta, as well as the encouraging potential of the combination of tobevibart and elebsiran,” said Mark Eisner, MD, MPH, Chief Medical Officer, Vir Biotechnology. “We are proud of our continued progress across the entire ECLIPSE program, and grateful to the physicians and patients choosing to join our trials.”

CHD is the most severe form of chronic viral hepatitis,<sup>1</sup> recently classified as carcinogenic by the International Agency for Research on Cancer.<sup>2</sup> People living with the disease rapidly progress to cirrhosis, liver failure<sup>3</sup> and liver-related death.<sup>1</sup> There are currently no approved treatments in the U.S., and options are limited in the European Union and globally. The objective is to eliminate the virus, and tobevibart in combination with elebsiran offers the potential to achieve this by tackling the viral lifecycle through multiple mechanisms.

The significant unmet need in CHD and the potential for the combination of tobevibart and elebsiran to provide a much-needed treatment option has been recognized by the U.S. Food and Drug Administration (FDA) with Breakthrough Therapy and Fast Track designations, and by the European Medicines Agency (EMA) with Priority Medicines (PRIME) and orphan drug designations.

## About the ECLIPSE Registrational Program

ECLIPSE is a registrational program to evaluate the safety and efficacy of tobevibart in combination with elebsiran in patients with chronic hepatitis delta (CHD). ECLIPSE includes three randomized, controlled trials designed to evaluate the combination therapy in comparison to deferred treatment or bulevirtide. ECLIPSE 1 (**NCT06903338**) is a Phase 3 trial evaluating the safety and efficacy of tobevibart in combination with elebsiran compared to deferred treatment in the U.S. or other regions where bulevirtide use is limited. ECLIPSE 2 (**NCT07128550**) is a Phase 3 trial that will evaluate the efficacy and safety of switching to tobevibart and elebsiran in people with CHD who have not achieved viral suppression with bulevirtide therapy. ECLIPSE 1 and 2 are designed to provide the registrational efficacy and safety data needed for potential submission to global regulatory agencies. ECLIPSE 3 (**NCT07142811**) is a Phase 2b head-to-head trial to evaluate tobevibart and elebsiran compared with bulevirtide in bulevirtide-naïve patients, and it is designed to provide important supportive data to help establish access and reimbursement in key markets.

## About Tobevibart and Elebsiran

Tobevibart is an investigational broadly neutralizing monoclonal antibody targeting the hepatitis B surface antigen (HBsAg). It is designed to inhibit the entry of hepatitis B and hepatitis delta viruses into hepatocytes and to reduce the level of circulating viral and subviral particles in the blood. Tobevibart was identified using Vir Biotechnology's proprietary monoclonal antibody discovery platform. The Fc domain has been engineered to increase immune engagement and clearance of HBsAg immune complexes and incorporates Xencor's Xtend™ technology to extend

half-life. Tobevibart is administered subcutaneously, and it is currently in clinical development for the treatment of patients with chronic hepatitis delta.

Elebsiran is an investigational hepatitis B virus-targeting small interfering ribonucleic acid (siRNA) discovered by Alnylam Pharmaceuticals, Inc. It is designed to degrade hepatitis B virus RNA transcripts and limit the production of hepatitis B surface antigen. Current data indicate that it has the potential to have direct antiviral activity against hepatitis B virus and hepatitis delta virus. Elebsiran is administered subcutaneously, and it is currently in clinical development for the treatment of patients with chronic hepatitis delta.

## About Vir Biotechnology, Inc.

Vir Biotechnology, Inc. is a clinical-stage biopharmaceutical company focused on powering the immune system to transform lives by discovering and developing medicines for serious infectious diseases and cancer. Its clinical-stage portfolio includes programs for chronic hepatitis delta and multiple dual-masked T-cell engagers across validated targets in solid tumor indications. Vir Biotechnology also has a portfolio of preclinical programs across a range of infectious diseases and oncologic malignancies. Vir Biotechnology routinely posts information that may be important to investors on its website.

### References:

<sup>1</sup> NIH National Institute of Diabetes and Digestive and Kidney Diseases **Hepatitis D - NIDDK (nih.gov)**, accessed September 2025

<sup>2</sup> Karagas, Margaret R et al., Carcinogenicity of hepatitis D virus, human cytomegalovirus, and Merkel cell polyomavirus, *The Lancet Oncology*, Volume 26, Issue 8, 994 – 995.

<sup>3</sup> CDC **What is Hepatitis D - FAQ | CDC**, accessed September 2025

## Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “should,” “could,” “may,” “might,” “will,” “plan,” “potential,” “aim,” “expect,” “anticipate,” “promising” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements regarding: the therapeutic potential of the combination of tobevibart and elebsiran to treat CHD and Vir Biotechnology’s belief that it can offer a much-needed new treatment option for these patients; Vir Biotechnology’s clinical development plans and expectations for the ECLIPSE Phase 3 registrational program, including protocols for and enrollment into ongoing and planned clinical studies, target endpoints and data readouts (including the expected primary completion of ECLIPSE 1 by year-end

2026); Vir Biotechnology's strategy and plans; and any assumptions underlying any of the foregoing. Many factors may cause differences between current expectations and actual results, including, without limitation: unexpected safety or efficacy data or results observed during clinical studies or in data readouts, including the occurrence of adverse safety events; risks of unexpected costs, delays or other unexpected hurdles; challenges in accessing manufacturing capacity; clinical site activation rates or clinical enrollment rates that are lower than expected; the timing and outcome of Vir Biotechnology's planned interactions with regulatory authorities, as well as general difficulties in obtaining any necessary regulatory approvals; successful development and/or commercialization of alternative product candidates by Vir Biotechnology's competitors, as well as changes in expected or existing competition; geopolitical changes or other external factors; and unexpected litigation or other disputes. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical studies may not be indicative of full results or results from later stage or larger scale clinical studies and do not ensure regulatory approval. The actual results may vary from the anticipated results, and the variations may be material. You are cautioned not to place undue reliance on any scientific data presented or these forward-looking statements, which are based on Vir Biotechnology's available information, expectations and assumptions as of the date of this press release. Other factors that may cause Vir Biotechnology's actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in Vir Biotechnology's filings with the U.S. Securities and Exchange Commission, including the section titled "Risk Factors" contained therein. Except as required by law, Vir Biotechnology assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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